



May 10, 2006

5-11-06 I7w  
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Mail Stop Non Fee Amendment  
Commissioner for Patents and Trademarks  
P.O. Box 1450  
Alexandria, VA 22313-1450

Re: Patent Application No.: 10/758,548  
Filing Date: 01/15/2004  
Titled: Vancomycin haemostatic paste composition  
Applicants: DHARAN, Murali et al.

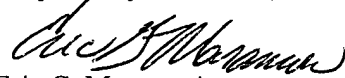
Dear Sir,

Please find enclosed the following documents:

1. Amendment (16 pages)
2. Return Post Card

Please confirm receipt of the above listed document by applying the date stamp to the enclosed post card. Please return the post card for our records.

Respectfully Submitted,


  
Eric G. Masamori  
Attorney for Applicants

Enclosures

**CERTIFICATE OF MAILING**

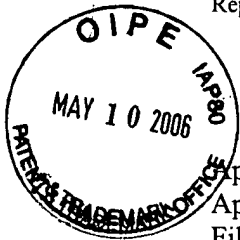
I hereby certify that this document and those referenced as attached, addressed to the Mail Stop Non Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 was deposited with the U.S. Postal Service as Express Mail Post Office to Addressee with sufficient postage at Castro Valley, CA on MAY 10, 2006

ED 888330071 US  
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Eric G. Masamori

Appl. No. 10/758,548  
Amdt. Dated May 10, 2006  
Reply to Office Action of February 23, 2006

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**



Applicant: Dharan, Murali et al.  
Appn. No.: 10/758,548  
Filed: January 15, 2004  
Title: Vancomycin Haemostatic Paste Composition

Grp. Art Unit: 1654  
Examiner: Chism, Billy D.

Mail Stop Non-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**AMENDMENT**

Sir,

In response to the Office Action of February 23, 2006, please amend the above-identified application as follows:

**Introductory Comments** begin on page 2 of this paper.

**Remarks** begin on page 5 of this paper.

**Conclusion** begins on Page 14 of this paper.

**Amendment to Claims** begin on page 15 of this paper.

### **Introductory Comments**

The Examiner has cited the following Objection/Rejections in this matter:

#### **Claim Objection**

The Examiner has objected to Claim 4 due to informality. Claim 4, line 2 comprises the term “expose” wherein the term should be the adjective “exposed”. The Examiner is requesting appropriate correction.

#### **Rejection under 35 USC § 102**

35 USC §102(b) forms the basis of a prior art rejection and states:

“A person shall not be entitled to a patent unless—

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.”

The Examiner has rejected Claims 1, 3-6 as being anticipated by Winkler et al. (2000, Journal of Antimicrobial Chemotherapy, Vol. 26, pages 423-428). The Examiner states that Winkler et al teach the use of vancomycin in water.

The Examiner further states that the intended use aspects of the claims were not considered as a limiting factor in the rejected claims for it is the product of the product claims that is under consideration and not the intended use.

#### **Rejection under 35 USC §103**

35 USC §103(a) forms the basis of an obviousness rejection and states:

“(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.”

The Examiner rejected Claims 1-10 under 35 USC 103(b) as being unpatentable over Winkler in combination with Vogt et al. (US 2004/0052841 A1).

The Examiner states that Winkler et al teach the use of powered vancomycin in water solution in bone graft studies. Winkler et al. teach vancomycin in water at 1 g/10 mL ration, however, Winkler et al. does not teach 1:1 vancomycin to water (weight to cubic centimeter volume). Winkler et al. teach the use for effects on bone repair and eradication of infection.

The Examiner states that Vogt et al. teach pharmaceutical compositions comprising vancomycin such as bone cements to treat bacterial infections in localized area in vivo. Vogt et al do not teach vancomycin in water or saline or Lactated Ringers.

The Examiner states the instant claims are to a composition comprising vancomycin with a biocompatible carrier, i.e., water, saline and Lactated Ringers. The Examiner states that the prior art teaches compositions comprising vancomycin with biocompatible carrier (Winkler and Vogt in combination). The Examiner further states that “the prior art teaches the use of such compositions for treatment of infections on the bone tissues of the body or for prevention of such infections due to insult to bony tissues (Winkler and Vogt). The prior art teaches the success of such techniques. Although the prior art does not teach a paste as claimed in your invention, the prior art teaches the application of the compositions to hard and soft tissues of the human and veterinary bodies as resorbable and non-resorbable implants.”

The Examiner states that “the prior use of vancomycin compositions for treatment of bony tissues for purposes of fighting infections while bony tissues repair or metallic or non-metallic implants are utilized. Even though Claims 2 and 7-10 are to a composition with a 1:1 vancomycin to carrier ration, from the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.” Therefore, the Examiner states, the “invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the

references, especially in the absence of evidence to the contrary, i.e., that a 1:1 ration had some unexpected result not obvious to one of skill in the art.”

The Examiner notes that the intended use aspects of the claims were not considered as limiting factor in the rejected claims for it is the product of the product claims that is under consideration and not the intended use.

### **Rejection under 35 USC §112**

35 USC §112 second paragraph states:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The Examiner has rejected Claims 4, 6 and 9 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The claims are indefinite for the recitation of the phrase “capable of” wherein it is unclear as to whether the “capable of” characteristic is what the compounds of the claims is specifically used for.

The balance of this response will respond to the Examiner’s concerns and each cited basis of objection/rejection.